

## PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 500496WO01	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/GB2004/005398	International filing date (day/month/year) 22.12.2004	Priority date (day/month/year) 22.12.2003
International Patent Classification (IPC) or both national classification and IPC A61K31/702		
Applicant BTG INTERNATIONAL LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  21.10.2005	Date of completion of this report  01.12.2005
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Bardili, W  Telephone No. +49 89 2399-2132  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB2004/005398

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-51 as originally filed

**Claims, Numbers**

1-76 as originally filed

**Drawings, Sheets**

1/11-11/11 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB2004/005398

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. 1-70, 73, 76 with respect to industrial applicability

because:

- ☒ the said international application, or the said claims Nos. 1-70, 73, 76 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (specify):

**see separate sheet**

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):  
☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.  
☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the Standard.  
☐ the computer readable form has not been furnished or does not comply with the Standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	75, 76
	No: Claims	1-74
Inventive step (IS)	Yes: Claims	
	No: Claims	1-76
Industrial applicability (IA)	Yes: Claims	71, 72, 74, 75
	No: Claims	

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/GB2004/005398**

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2. Citations and explanations

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB2004/005398

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claims 1-70, 73 and 76 relate to medical treatment of the human body and hence to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Claim 74 is related to a pharmaceutical composition comprising one or more of the compounds recited in claims 1-68. As explained in the application at page 7, lines 5-7 of the description these compounds may be obtained from fenugreek seeds by an extraction process. The therapeutic activity of fenugreek seeds was well-known at the filing date of the application, see for instance the references cited in D1/ WO-A-99 25 19, in particular at page 3, 2<sup>nd</sup> paragraph (Sharma 1986; Madar 1984; Ribes et al.1984) or the documents D2/ US-A-6 451 355 and D3/ WO-A-98 33 494, cited in the search report, which disclose the medical use of fenugreek seeds in certain forms of combination therapy (D2: claim 1; D3: claim 8). In all these references fenugreek seeds as such are used to prepare pharmaceutical compositions. Thus, claim 74 lacks novelty over each of these references.

The applicants appear to be of the opinion that the structural description of the active ingredients contained in fenugreek seeds according to claims 1-68 would distinguish their preparations over the prior art. The examiner disagrees since a new description of a known composition does not render the composition novel.

The applicants also appear to be of the opinion that the claimed pharmaceutical compositions would be novel owing to the biological effects described in the application. It should be noted, however, that the effects of a composition are not a technical feature of the composition and therefore irrelevant to claim 74 in the given context.

2. Claim 1 is directed to the therapeutic treatment of diseases involving enhanced activity

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB2004/005398

of core 2 GlcNAc-transferase by suitable inhibitors of this enzyme. The diseases to be treated are *inter alia* diabetic retinopathy, diabetic cardiomyopathy, atherosclerosis, or cancer. The inhibitors are steroids bearing a glycoside at C-3. Compounds having these structural characteristics have been used in the prior art to prepare medicaments for the treatment of diabetic retinopathy, cardiomyopathy, atherosclerosis and cancer, see in particular D3, D4/ US-A-4 602 003 (example 3), and D6/ J. Org. Chem. 68, 3658 (2003). It appears therefore that claims 1-73 lack novelty.

3. The compound of claim 75 is novel. Inventive step, however, cannot be acknowledged in the absence of any data demonstrating a pharmaceutical activity of this compound.